

## § 522.313

wounds) in dogs caused by susceptible strains of *Staphylococcus intermedius* and *Streptococcus canis* (Group G).

(2) *Cats*—(i) *Amount*. Administer 3.6 mg/lb (8 mg/kg) body weight as a single, one-time subcutaneous injection.

(ii) *Indications for use*. For the treatment of skin infections (wounds and abscesses) in cats caused by susceptible strains of *Pasteurella multocida*.

[73 FR 29685, May 22, 2008]

### § 522.313 Ceftiofur injectable dosage forms.

#### § 522.313a Ceftiofur crystalline free acid.

(a) *Specifications*. The product is a suspension of ceftiofur crystalline free acid.

(1) Each milliliter (mL) contains 100 milligrams (mg) ceftiofur equivalents.

(2) Each mL contains 200 mg ceftiofur equivalents.

(b) *Sponsor*. See No. 000009 in § 510.600(c) of this chapter.

(c) *Related tolerances*. See § 556.113 of this chapter.

(d) *Special considerations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(e) *Conditions of use*—(1) *Swine*. The formulation described in paragraph (a)(1) of this section is used as follows:

(i) *Amount*. 5.0 mg CE per kilogram (kg) of body weight by intramuscular injection in the postauricular region of the neck.

(ii) *Indications for use*. For the treatment of swine respiratory disease (SRD) associated with *Actinobacillus pleuropneumoniae*, *Pasteurella multocida*, *Haemophilus parasuis*, and *Streptococcus suis*. For the control of SRD associated with *A. pleuropneumoniae*, *P. multocida*, *H. parasuis*, and *S. suis* in groups of pigs where SRD has been diagnosed.

(iii) *Limitations*. Following label use as a single treatment, a 14-day pre-slaughter withdrawal period is required.

(2) *Cattle*. The formulation described in paragraph (a)(2) of this section is used as follows:

(i) *Amount*. 6.6 mg ceftiofur equivalents per kg of body weight as a single injection. For subcutaneous injection in the middle third of the posterior aspect of the ear or in the posterior as-

## 21 CFR Ch. I (4–1–12 Edition)

pect of the ear where it attaches to the head (base of the ear) in beef and non-lactating dairy cattle. For subcutaneous injection in the posterior aspect of the ear where it attaches to the head (base of the ear) in lactating dairy cattle.

(ii) *Indications for use*. For the treatment of bovine respiratory disease (BRD, shipping fever, pneumonia) associated with *Mannheimia haemolytica*, *Pasteurella multocida*, and *Histophilus somni* in beef, non-lactating dairy, and lactating dairy cattle. For the control of respiratory disease in beef and non-lactating dairy cattle which are at high risk of developing BRD associated with *M. haemolytica*, *P. multocida*, and *H. somni*. For the treatment of bovine foot rot (interdigital necrobacillosis) associated with *Fusobacterium necrophorum* and *Porphyromonas levis* in beef, non-lactating dairy, and lactating dairy cattle.

(iii) *Limitations*. Following label use as a single treatment, a 13-day pre-slaughter withdrawal period is required. A withdrawal period has not been established in preruminating calves. Do not use in calves to be processed for veal.

(3) *Horses*. The formulation described in paragraph (a)(2) of this section is used as follows:

(i) *Amount*. Two intramuscular injections, 4 days apart, at a dose of 3.0 mg/lb (6.6 mg/kg) body weight.

(ii) *Indications for use*. For the treatment of lower respiratory tract infections in horses caused by susceptible strains of *Streptococcus equi* ssp. *zooepidemicus*.

(iii) *Limitations*. Do not use in horses intended for human consumption.

[68 FR 60296, Oct. 22, 2003, as amended at 69 FR 43892, July 23, 2004. Redesignated and amended at 71 FR 39546, July 13, 2006; 73 FR 58872, Oct. 8, 2008; 75 FR 4692, Jan. 29, 2010; 75 FR 62468, Oct. 12, 2010]

#### § 522.313b Ceftiofur hydrochloride.

(a) *Specifications*. Each milliliter of ceftiofur hydrochloride suspension contains 50 milligrams (mg) ceftiofur equivalents.

(b) *Sponsor*. See No. 000009 in § 510.600(c) of this chapter.

(c) *Related tolerances*. See § 556.113 of this chapter.

(d) Special considerations. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(e) *Conditions of use.* (1) *Swine*—(i) *Amount.* 3 to 5 mg per kilogram (/kg) of body weight by intramuscular injection. Treatment should be repeated at 24-hour intervals for a total of 3 consecutive days.

(ii) *Indications for use.* For treatment and control of swine bacterial respiratory disease (swine bacterial pneumonia) associated with *Actinobacillus pleuropneumoniae*, *Pasteurella multocida*, *Salmonella Choleraesuis*, and *Streptococcus suis*.

(iii) *Limitations.* Treated swine must not be slaughtered for 4 days following the last treatment.

(2) *Cattle*—(i) *Amount.* For bovine respiratory disease and acute bovine interdigital necrobacillosis, administer 1.1 to 2.2 mg/kg of body weight at 24-hour intervals for 3 to 5 consecutive days. For bovine respiratory disease only, 2.2 mg/kg of body weight may be administered twice at a 48-hour interval. For acute metritis only, administer 2.2 mg/kg of body weight at 24-hour intervals for 5 consecutive days. Product in peanut oil suspension may be administered by either intramuscular or subcutaneous injection. Product in caprylic/capric triglyceride suspension may be administered by subcutaneous injection only.

(ii) *Indications for use.* For treatment of bovine respiratory disease (BRD, shipping fever, pneumonia) associated with *Mannheimia haemolytica*, *P. multocida*, and *Histophilus somni*; acute bovine interdigital necrobacillosis (foot rot, pododermatitis) associated with *Fusobacterium necrophorum* and *Bacteroides melaninogenicus*; and acute metritis (0 to 14 days post-partum) associated with bacteria susceptible to ceftiofur.

(iii) *Limitations.* Treated cattle must not be slaughtered for 3 days following the last treatment. A withdrawal period has not been established in

preruminating calves. Do not use in calves to be processed for veal.

[61 FR 29479, June 11, 1996, as amended at 63 FR 53578, Oct. 6, 1998; 67 FR 45901, July 11, 2002; 69 FR 47362, Aug. 5, 2004. Redesignated and amended at 71 FR 39544, July 13, 2006; 73 FR 45612, Aug. 6, 2008; 76 FR 17338, Mar. 29, 2011]

#### §522.313c Ceftiofur sodium.

(a) *Specifications.* Each milliliter of aqueous solution constituted from ceftiofur sodium powder contains 50 milligrams (mg) ceftiofur equivalents.

(b) *Sponsors.* See Nos. 000009 and 068330 in §510.600(c) of this chapter.

(c) *Related tolerances.* See §556.113 of this chapter.

(d) *Special considerations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(e) *Conditions of use*—(1) *Swine*—(i) *Amount.* 3 to 5 mg per kilogram (/kg) body weight by intramuscular injection for 3 consecutive days.

(ii) *Indications for use.* For treatment and control of swine bacterial respiratory disease (swine bacterial pneumonia) associated with *Actinobacillus pleuropneumoniae*, *Pasteurella multocida*, *Salmonella choleraesuis*, and *Streptococcus suis*.

(iii) *Limitations.* Treated pigs must not be slaughtered for 4 days following the last treatment.

(2) *Cattle*—(i) *Amount.* 0.5 to 1.0 mg/lb body weight by intramuscular or subcutaneous injection for 3 days. Additional treatments may be given on days 4 and 5 for animals which do not show satisfactory response.

(ii) *Indications for use.* For treatment of bovine respiratory disease (shipping fever, pneumonia) associated with *Mannheimia haemolytica*, *P. multocida*, and *Histophilus somni* in beef and dairy cattle; and for treatment of acute bovine interdigital necrobacillosis (foot rot, pododermatitis) associated with *Fusobacterium necrophorum* and *Bacteroides melaninogenicus*.

(iii) *Limitations.* Treated cattle must not be slaughtered for 4 days following the last treatment.

(3) *Sheep*—(i) *Amount.* 0.5 to 1.0 mg/lb body weight by intramuscular injection for 3 days. Additional treatments